IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., ABBOTT BIOTECHNOLOGY, LTD. Plaintiffs, v. CENTOCOR ORTHO BIOTECH, INC., CENTOCOR BIOLOGICS, LLC. Defendant.	C.A. No. 4:09-CV-11340 (FDS) JURY TRIAL DEMANDED

ABBOTT'S OPPOSITION TO CENTOCOR'S MOTION TO AMEND CLAIM CONSTRUCTION PLEADINGS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

I. INTRODUCTION

Centocor[1] improperly attempts to assert a new non-infringement theory that requires the construction of a new claim term over six months following the parties' exchange of disputed claim terms, almost five months following the deadline for amending non-infringement contentions without leave of Court, and nearly four months following the *Markman* hearing. Centocor's motion was filed just days before the end of fact discovery, which closed on February 28, 2011. Centocor's belated non-infringement theory is based on (a) an alleged definition of the term "human antibody" set forth in the common specification of the patents-in-suit and (b) the amino acid sequence of Centocor's antibody, information that was known to Centocor long before this litigation was instituted in August of 2009. Centocor's effort to raise this issue for the first time at this point in the litigation not only underscores the dubious nature of Centocor's arguments but is also unfairly and unduly prejudicial because it comes far too late.

As this Court previously recognized in *Abbott Laboratories et al. v. Bayer Healthcare LLC*, Civil Action No. 4:09-cv-40002 (FDS), untimely attempts to inject new theories of non-infringement into a case, particularly those that require the belated construction of a new claim term, are inappropriate. Non-infringement contentions serve no purpose if a party can wait until the end of discovery to shift course and start litigating based on new positions that have never been disclosed to the other side. For this reason, this Court entered a scheduling order that required infringement and non-infringement contentions be amended no later than 30 days before the claim construction hearing, except "by leave of court, for good cause shown." (*See* Scheduling Order (Mar. 2, 2010) Dkt. No. 44 ("Scheduling Order") at ¶ 1(b)-(c).)

[1] Defendants Centocor Ortho Biotech, Inc. and Centocor Biologics, LLC are collectively referred to herein as Centocor. Plaintiffs Abbott GmbH & Co., KG, Abbott Bioresearch Center, Inc., and Abbott Biotechnology Ltd. are collectively referred to herein as Abbott.

In *Bayer*, the Court rejected Abbott's attempt to amend its non-infringement contentions and add a new claim term eight days before the close of fact discovery. (Gunther Decl.[2] Ex. 1, *Bayer* Transcript of Telephonic Status Conference (Oct. 20, 2010); Gunther Decl. Ex. 2, Bayer Healthcare LLC's Motion to Strike Abbott's Amended Non-Infringement Contentions (July 20, 2010).) Here, Centocor waited just five days before the close of fact discovery to seek leave to amend its infringement contentions to add an entirely new non-infringement theory based on an entirely new claim construction theory. (*See* Defs.' Mot. for Leave to File Am. Preliminary Invalidity and Non-Infringement Contentions (Feb. 23, 2011), Dkt. No. 122 ("Mot. to File Am. Contentions").) For the reasons set forth herein, the Court should reject this untimely request because 1) Centocor has not met its burden of showing good cause for asserting a new non-infringement theory so late in the proceedings, and 2) Centocor has failed to demonstrate that the "human antibody" claim term it now seeks to construe as part of this theory is defined in a portion of the common specification on which it relies.

II. CENTOCOR'S UNTIMELY ATTEMPT TO ASSERT A NEW NON-INFRINGEMENT THEORY SHOULD BE REJECTED

A. Centocor Waited Until the Eve of the Close of Fact Discovery to Assert Its New Non-Infringement Theory

Abbott filed this case on August 10, 2009. Fact discovery began on February 1, 2010. Pursuant to the Scheduling Order set by the Court, on March 25, 2010, Abbott served its Preliminary Infringement Contentions and produced supporting documents. (*See* Scheduling Order at ¶ 1(b).) Over the next few months, the parties exchanged another set of infringement contentions and two sets of invalidity and non-infringement contentions, before exchanging disputed claim terms and proposed constructions on August 20, 2010. (*See id.* at 3(a).) Each

[2] The Declaration of Robert J. Gunther in Support of Abbott's Opposition to Centocor's Motion to Amend Claim Construction Pleadings, dated March 7, 2011, and filed contemporaneously with this brief, is referred to herein as "Gunther Decl."

party then served another set of amended contentions on October 8, 2010, the last day to amend or supplement contentions without leave of Court. (*See id.* at ¶ 1(b)-(c) (permitting disclosures to "be amended or supplemented up to 30 days before the date of the Markman Hearing. After that time, such disclosures may be amended or supplemented only by leave of court, for good cause shown.").)

Following comprehensive claim construction briefing, the Court held a *Markman* hearing on November 9, 2010. (*See* Dkt. Nos. 81-82, 86-87; Markman Hearing (Nov. 9, 2010).) Not only did the parties file opening and reply claim construction briefs and a joint claim construction and prehearing statement prior to the *Markman* hearing, but the Court also permitted the parties to file post-hearing briefs. (*See* Dkt. Nos. 100-101; 104-106.) In addition, on January 10, 2011, the Court granted Centocor leave to file a response to Abbott's post-hearing brief, and Centocor did so on January 18. (*See* Order on Motion for Leave to File (Jan. 10, 2011); Dkt. No. 114.)

At no point during the extensive *Markman* process in this litigation did Centocor hint that the term "human antibody" needed construction. Likewise, at no point in the first year and a half of the litigation did Centocor assert that its accused product, Stelara, is not a human antibody, despite the fact that Abbott stated in *each* of its infringement contentions that the Stelara product label and the European (EMEA) Summary of Product Characteristics of Stelara specifically describe Stelara as a human antibody. (*See, e.g.*, Gunther Decl. Ex. 3, Excerpt from Abbott's Preliminary Infringement Contentions (Mar. 25, 2010) at 8, 13 (discussing Exhibits B and C); Gunther Decl. Ex. 4, Excerpt from Abbott's Second Supplemental Preliminary Infringement Contentions (Oct. 8, 2010) at Exhibit 6, 12 (discussing Exhibits B and C); *see* Gunther Decl. Ex. 5, Stelara Label or "Medication Guide" approved by the U.S. Food and Drug Administration,

U.S. License No. 1821 at ABT-IL-12-00000008 (confirming that [redacted]); Gunther Decl. Ex. 6, EMEA Annex I Summary of Product Characteristics of Stelara at ABT-IL-12-00000018) (same).)

Instead, Centocor waited until January 31, 2011 – just one month before the close of fact discovery – to propose to Abbott that the term "human antibody" should be construed. By that time, the deadline to serve final written discovery had passed, and Abbott had already taken seventeen depositions and Centocor had taken nineteen, with only a handful remaining for each side. Even when Centocor proposed this new construction, it made no effort to seek leave to amend its non-infringement contentions, leaving Abbott to guess what that position would be. While Centocor served some discovery in late January that gave Abbott an inkling as to where this new "human antibody" theory might be going, Centocor did not present Abbott or this Court with a proposed new set of non-infringement contentions until February 23 – just five days before the close of fact discovery. (*See* Gunther Decl. Ex. 7, Defendants' Sixth Set of Interrogatories (Nos. 16-19) (Jan. 20, 2011); Gunther Decl. Ex. 8, Defendants' First Set of Requests for Admission (Nos. 1-3) (Jan. 20, 2011); Mot. to File Am. Contentions.)

B. There Was No Legitimate Reason for Centocor's Delay

While Centocor now argues that it somehow realized that "human antibody" was a term to construe only after taking the deposition of Abbott inventor Michael White on January 28, 2011 (*see* Mem. in Supp. of Mot. to Amend Claim Construction Pleadings ("Centocor Mem.") at 5), this explanation is specious. As Centocor itself points out, each of the asserted claims recites the term "human antibody." (*Id.* at 3.) Centocor was fully aware of the use of this term in the patents-in-suit, as well as the amino acid sequence of its own antibody, throughout the litigation and well before the litigation commenced. Indeed, Centocor had already requested an interference proceeding with the United States Patent and Trademark Office's Board of Patent

Appeals and Interferences ("BPAI") in December 2007, alleging that Centocor had invented its competing human anti-IL-12 antibody, ustekinumab, prior to Abbott's invention of the claimed antibodies in U.S. Patent 6,914,128 ("'128 Patent"). (*See* Gunther Decl. Ex. 9, Centocor's Declaration of Interference.) As such, Centocor was well aware of the term "human antibody," its definition, and application of this term to its own product, at least by December 2007.

There is nothing new that Centocor has discovered about the term "human antibody" in the course of fact discovery that it did not already know by August, when the parties exchanged disputed claim terms, let alone by October, when the parties exchanged their last sets of respective amended contentions without leave of Court. Likewise, Mr. White's testimony about the purpose and process of germline sequencing for Abbott's anti-IL-12 antibody (*see* Pearson Decl. in Supp. of Centocor Mem. ("Pearson Decl.") Ex. 8, White Tr. (Jan. 28, 2011) 56-57) revealed nothing new that Centocor did not already know based on various descriptions in the patents-in-suit. (*See e.g.*, Pearson Decl. Ex. 5, '128 Patent Figure 1, col.25 l.42-col.26 l.14, col.30 ll.34-41, col.44 l.44-col.45 l.42, col.48 ll.22-25, col.65 ll.42-43.[3]) Further, Centocor was already seeking fact discovery relating the term "human antibody" more than a week before Mr. White's deposition, without having yet presented Abbott with its new non-infringement position, or its new request for construction. (*See* Gunther Decl. Exs. 7-8.)

C. Centocor's Untimely Attempt to Assert a New Non-Infringement Theory Based on a New Claim Construction Term is Unfairly Prejudicial and Inappropriate

Fact discovery is now closed, and while Centocor has served discovery requests relating to this issue on Abbott, Centocor's delay in presenting its new non-infringement theory has

[3] The '128 Patent and U.S. Patent 7,504,485 ("'485 Patent") (collectively "the patents-in-suit") have nearly identical specifications, and therefore, citations to the patents' common specification are to that of the '128 Patent, unless specified otherwise.

effectively precluded Abbott from taking any reciprocal fact discovery on this point. Fact discovery would be necessary, however, to assess the proper application of Centocor's proposed construction of the term "human antibody" to the structure of Centocor's antibody. For instance, Abbott would want to take discovery on Centocor's own human germline analyses, and its characterizations of the accused product as a human antibody in light of the same. (*See, e.g.*, Gunther Decl. Ex. 10, Centocor Technical Report at COBI00614912-13 ([redacted]); Gunther Decl. Ex. 11, COBI007450548-49 ([redacted]).)

Centocor suggests that its non-infringement theory and construction would simply require a comparison of sequences to Kabat et al. (1991) *Sequences of proteins of Immunological Interest, Fifth Edition*, U.S. Department of Health and Human Services, NIH Publication No. 91-3242. (*See* Centocor Mem. at 1.) This 1991 hard-copy edition of the Kabat listing of germline sequences, which Centocor asserts should be used to run an expert analysis of sequences (*see id.*), has been replaced by an electronic Kabat database, which was updated with additional sequences until 2003. *See* http://www.kabatdatabase.com/index.html. These new sequences are not included in the Kabat book, but are accepted as additional human germline immunoglobulin sequences identified since 1991. (Gunther Decl. Ex. 12, Johnson and Wu, "Kabat database and its applications: 30 years after the first variability plot," *Nucleic Acids Research,* 2000, Vol. 28, No. 1, 214 ("Massive amounts of sequence data are being continuously published in the scientific literature . . . We have previously published five editions of these sequences . . . In 1991, the fifth edition (2) consisted of three volumes. Currently, the database is more than five times as large.").) Comparing sequences with the 1991 version of the Kabat reference book, as Centocor suggests, would likely result in outdated results, as such comparisons are now run

electronically, against one of several sequencing databases, including an updated Kabat database, or the VBase database referenced throughout the common specification of the patents. This issue would have been the proper subject of fact discovery, had Centocor's new position not come so late in the case.

Furthermore, the process of running sequence comparisons based on the 1991 version of the Kabat book is not nearly as simple as Centocor suggests. (*See* Centocor Mem. at 1.) Not only is the process of comparing sequences to a hard-copy book outdated and no longer familiar to scientists in this field, but this particular book is more than 2,500 pages long, making the task of accurately determining whether Centocor's antibody corresponds to and/or differs by up to 20 amino acids from one of the germline amino acid sequences listed in the book laborious. Accordingly, the consequences of adding Centocor's novel non-infringement position based on a new claim term to the litigation would likely cause substantial delays that would further prejudice Abbott.

In addition, Abbott would need to take fact and expert discovery concerning the nature of the specific changes in the sequence of the Centocor antibody to develop positions with respect to literal infringement and infringement under the doctrine of equivalents. That discovery would necessarily require a detailed examination of how and why the changes occurred and the insubstantiality of those changes in terms of whether the Centocor antibody would infringe the "human antibody" term as construed by Centocor under the doctrine of equivalents.

For all of these reasons, just as this Court rejected an attempt by Abbott to present a new non-infringement theory based on a new claim term days before the close of fact discovery in the *Bayer* case, it should, likewise, reject Centocor's untimely attempt to do the same here.

III. CENTOCOR'S CONSTRUCTION OF THE TERM HUMAN ANTIBODY SHOULD BE REJECTED

As discussed in detail below, the fallacy of Centocor's new non-infringement theory is further underscored by the exemplary nature of the patent specification language on which this theory relies, as well by Centocor's inconsistent positions regarding the term "human antibody" in the interference proceeding. Nevertheless, if the Court does permit Centocor to inject its new non-infringement theory into this litigation, Abbott respectfully requests that, for the reasons discussed below, the Court construe the term "human antibody" as "an antibody that is derived from human DNA and not from the DNA of any non-human species."

"human antibody"	
ABBOTT'S PROPOSED CONSTRUCTION	**CENTOCOR'S PROPOSED CONSTRUCTION**
"An antibody that is derived from human DNA and not from the DNA of any non-human species."	"A human antibody includes antibodies having variable and constant regions corresponding to human germline immunoglobulin sequences as described by Kabat et al. (See Kabat, et al. (1991) Sequences of proteins of Immunological Interest, Fifth Edition, U.S. Department of Health and Human Services, NIH Publication No. 91-3242), but the antibody can have up to twenty positions replaced with amino acid residues which are not part of the human germline immunoglobulin sequence."

A. The Specification Description Following the Term "Human Antibody" is Exemplary and Not Definitional

Centocor's new non-infringement and claim construction positions are premised on the erroneous notion that the specifications of the patents-in-suit explicitly define the term "human antibody." To the contrary, the relevant specification language states that the term "human antibody" *includes* antibodies with certain exemplary characteristics. However, nothing in the

patents-in-suit, the prosecution histories of the patents, or Abbott's prior statements limits this term to antibodies with those particular exemplary characteristics.

Centocor points to the following specification language as a definition of the term "human antibody":

> The term "human antibody" **includes** antibodies having variable and constant regions corresponding to human germline immunoglobulin sequences as described by Kabat et al. (See Kabat, et al. (1991) *Sequences of proteins of Immunological Interest, Fifth Edition*, U.S. Department of Health and Human Services, NIH Publication No. 91-3242). The human antibodies of the invention **may include** amino acid residues not encoded by human germline immunoglobulin sequences (e.g., mutations introduced by random or site-specific mutagenesis in vitro or by somatic mutation in vivo), for example in the CDRs and in particular CDR3. The mutations preferably are introduced using the 'selective mutagenesis approach' described herein. The human antibody **can have** at least one position replaced with an amino acid residue, e.g., an activity enhancing amino acid residue which is not encoded by the human germline immunoglobulin sequence. The human antibody **can have** up to twenty positions replaced with amino acid residues which are not part of the human germline immunoglobulin sequence. In other embodiments, up to ten, up to five, up to three or up to two positions are replaced. In a preferred embodiment, these replacements are within the CDR regions as described in detail below. However, the term "human antibody", as used herein, **is not intended to include** antibodies in which CDR sequences derived from the germline of another mammalian species, such as a mouse, have been grafted onto human framework sequences.

('128 Patent at col. 26:55-27:14 (emphasis added).) From this language, Centocor concludes that its antibody does not infringe the patents-in-suit because it does not have variable and constant regions that completely correspond to one of the germline amino acid sequences listed in the 1991 edition of Kabat and because it differs by more than twenty 20 amino acid positions from one of the specified germline sequences in the same book. (Centocor Mem. at 3; Ex. A to Mot. to File Am. Contentions at 65.)

However, as the Court noted during the February 11, 2011 conference when this issue was first brought to its attention, the asserted patents' use of the term "includes" indicates that what is discussed is exemplary rather than definitional – a human antibody can have the

characteristics outlined in the specification description, but can also have other characteristics, just as "[t]he term 'Pittsburgh Steeler' includes Ben Roethlisberger and Troy Polamalu, but it includes lots of other people as well."[4] (Gunther Decl. Ex. 13, Status Conference Tr. (Feb. 11, 2011) at 14:12-14.). *See, e.g.*, *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1284 (Fed. Cir. 2005) ("As a patent law term of art, 'includes' means 'comprising.' . . . Neither includes, nor comprising, forecloses additional elements that need not satisfy the stated claim limitations."). Nothing in the specification excludes an antibody that does not completely correspond to one of 1991 Kabat germline sequences or that has more than twenty replaced amino acid positions.

This reading of the specification is further supported by the fact that the specification discusses the comparison based on a 1991 edition of the Kabat sequencing reference book, rather than a sequencing database. As discussed *supra* in section I(C), Kabat sequencing data is now an electronic database that has been updated with additional sequences since 1991. *See* http://www.kabatdatabase.com/index.html. It would not make sense that the patents-in-suit would be limited to antibodies with twenty or fewer changes in amino acid positions as compared to a particular edition of a Kabat book that is now outdated and does not provide an accurate comparison to human germline. Furthermore, throughout the common specification, including in Figure 1 and Appendix A, Table 1 of the patents, an electronic database called Vbase, and not the Kabat book, is used to compare Abbott's exemplary antibodies, including the clones designated Y61 and J695, to germline sequences. (Pearson Decl. Ex. 5, '128 Patent at col.25 ll.52-59, col.41 ll. 1-8, col.44 ll. 44-47, col.104 ll.29-32, Appendix A, Table 1.) The

[4] Even Centocor's proposed construction does not resolve this issue, as it incorporates the word "includes" into the proposed definition of "human antibody." This proposed circular definition continues to allow a human antibody to have the characteristics discussed in the proposed construction, but allows for other characteristics as well.

VBase database, as used by the patents' inventors in 1999 when the provisional application was filed, contained germline sequences that were discovered after 1991, which the 1991 version of the Kabat book would not have had. *See* http://vbase.mrc-cpe.cam.ac.uk/. For these additional reasons, the most rational reading is that the common specification refers to the specific edition of Kabat by way of example.

In addition, based on the patents' comparison of the variable regions of the heavy chain and light chain of Abbott's exemplary antibodies to the germline sequences in the VBase database, many of the antibodies have more than twenty positions replaced with amino acid residues which are not part of the human germline immunoglobulin sequence. (*See* Pearson Decl. Ex. 5, '128 Patent, Fig. 1, col. 23, l. 58 to col. 24, l. 5, Appendix A, Table 1.) This indicates that Centocor's proposed construction of "human antibody" may improperly exclude preferred embodiments disclosed in the patents, a result the Federal Circuit has stated is "rarely, if ever, correct." *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276-77 (Fed. Cir. 2008) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583-84 (Fed. Cir. 1996)).

Centocor's construction may also exclude the preferred embodiments depending on which portion of the antibody is compared to the germline sequences in the Kabat book (or the Kabat or VBase databases, for that matter). Centocor's construction simply states that the "variable and constant regions" of an antibody must be compared to germline. However, not all of the portions within those regions would necessarily be counted when comparing to germline

sequences.[5] Whether the antibodies in this case, including the preferred embodiments in the patent and the accused product, have more than twenty amino acid position changes when compared to germline depends on which portion of the antibody is or is not counted, and this is a determination that an expert would need to make. The non-exclusionary nature of the specification's exemplary language is juxtaposed and underscored by the specific exclusion in the last line of the specification passage, which explicitly states that "human antibody" does not include antibodies with sequences "derived from the germline of another mammalian species, such as a mouse . . . ." ('128 Patent at col.27 ll.12-13.) Abbott's proposed construction of "human antibody" as "an antibody that is derived from human DNA and not from the DNA of any non-human species" accounts for the exclusion, without improperly narrowing the term based on exemplary language, and, therefore, would be the correct construction to adopt if the Court were to reach this issue. Centocor's proposed construction, on the other hand, completely leaves out this relevant exclusionary language. Rather, Centocor attempts to construe this term based only on exemplary language in the specification, and even then, on just two pieces of the exemplary language that are most convenient for Centocor. This interpretation is simply unsupported by the full language of the patents.

B. Abbott's Prior Statements Are Consistent With Its Current Position

Centocor's argument that the interference proceeding testimony of Abbott's expert, Dr. Brent Iverson, contradicts Abbott's current position with regard to the term "human antibody" (Centocor Mem. at 10-11) is a red herring. When assessed in the full context of his declaration,

[5] Notably, an person of ordinary skill in the art would likely agree that only the framework regions of an antibody, and not the complementarity determining regions (CDRs) of the variable regions should be counted in comparing to germline sequences. This is because CDRs are key portions of antibodies that are naturally varied to give antibodies their unique binding characteristics, and changing the CDRs will change the antibodies' binding characteristics instead of just bringing the antibody closer to a human germline. (*See* Gunther Decl. Ex. 14, Janis Kuby, Immunology (3d ed. 1997), 113-115.) Further, in terms of the threshold of 20 amino acid differences, an expert would need to provide insight as to whether the 20 differences are counted with respect to a full antibody having two heavy and two light chains, or some portion thereof.

Dr. Iverson's statement does not limit the term "human antibody" to the reading Centocor suggests, and in no way attempts to exclude prior art based on the exemplary specification language on which Centocor relies. Rather, Dr. Iverson's statement focuses on the exclusionary language in the last line of the relevant specification passage, in order to distinguish prior art that discloses non-human mouse and rat antibodies.

Specifically, Dr. Iverson's declaration states:

> 15. Abbott's '128 Patent defines "human antibody" as follows: "The term 'human Antibody" includes antibodies having variable and constant regions corresponding to human germline immunoglobulin sequences as described by Kabat et al.... and ... **is not intended to include antibodies in which CDR sequences derived from the germline of another mammalian species, such as a mouse, have been grafted onto human framework sequences."**
>
> **16. All of the IL-12 references relied on by Centocor disclose research antibody sequences from non-humans considered suitable only for use in laboratory studies by virtue of their origin (e.g., Valiante and Trinchieri disclose a mouse antibody; Chizzonite and Trinchieri disclose a rat antibody).**
>
> 17. One of ordinary skill in the art as of March of 1999 would appreciate the traditional scientific distinction between a non-human antibody sequence and a human antibody sequence based on the species origin of the sequences.

(Pearson Decl. Ex. 12, Iverson Decl. at 5 (citations omitted; truncation in original; emphasis added).) Contrary to Centocor's assertions (*see* Centocor Mem. at 11), Abbott and Dr. Iverson never relied on the exemplary language in the relevant portion of the specification to distinguish prior art in order to avoid a ruling of obviousness in the interference. In fact, Dr. Iverson's declaration does not even mention the "twenty positions replaced with amino acid residues" language on which Centocor now relies. Instead, Abbott and Dr. Iverson relied on the language in the final line of the specification passage, which excludes antibodies with sequences derived

from non-human germlines, to distinguish prior art relating to non-human antibodies. This is further confirmed by Dr. Iverson's subsequent deposition testimony in the interference:

> Q. What degree of similarity to a human germline immunoglobulin sequence, as described at Kabat, et al. in your opinion is necessary to meet the '128 patent definition of human antibody?
>
> A. I believe the term "human antibody" refers to an antibody that is derived from a human as well as derivatives of that sequence in which changes have been made that enhance properties. This is distinct from sequences derived from antibodies from other – from other species that have been grafted in.

(Gunther Decl. Ex. 15, Iverson Tr. (June 6, 2008) at 63:5-15.) And in ruling in Abbott's favor on the issues of priority and obviousness in the interference, the BPAI did not adopt or rely on the specification's language concerning the number of changes from human germline in any way whatsoever, but, rather, reiterated that "'[h]uman antibodies' means human not part human and part something else." (*See* Gunther Decl. Ex. 16, BPAI Memorandum Opinion (Aug. 6, 2009), at 27.)

Abbott's proposed construction of the term "human antibody" specifically accounts for this exclusion and for Dr. Iverson's interpretation of the specification, as it proposes to include antibodies "derived from human DNA" but not those derived "from the DNA of any non-human species." Accordingly, Dr. Iverson's statements in the interference do not change the exemplary nature of the specification language at issue. Rather, they support Abbott's proposed claim construction of the term "human antibody."

Centocor also misstates the testimony of Abbott's expert, Dr. Marks, in the litigation *Centocor, Inc., et al. v. Abbott Laboratories, et al.*, Civil Action No. 2:07cv139 (TJW). Centocor incorrectly argues that Dr. Marks took the position that "'human' when used to describe an antibody can mean different things in different contexts." (Centocor Mem. at 3.) However, what Dr. Marks actually said is that when he uses the word "defined" when referring

to the patent specification in that litigation, he is referring to the meaning of a word "as determined by the contents, specifications, of that patent," and that a particular word, "[f]or example, the word human in referring to an antibody[,]" could be different in the context of one particular specification, as opposed to another. (Pearson Decl. Ex. 3, Marks Tr. (Oct. 21, 2008) at 89:14-90:4) Dr. Marks went on to testify that, based on the particular specifications of U.S. Patents 7,070,775 and 7,276,239 at issue in that litigation, the word "human" as used in those patents, neither of which are at issue in this case, is defined narrowly to mean "an antibody that is humanized," rather than "an antibody that is fully human in sequence." (*Id.* at 90:5-12.) Nothing about Dr. Marks' testimony suggested the term human does not have a plain meaning. In any case, this testimony has no bearing on the issue here.[6]

For this same reason, Centocor's focus on the language of other patents, such as U.S. Patent Nos. 7,223,394 and 7,541,031 is also inapposite. (*See* Centocor Mem. at 12.) It is well-settled law that "[a] particular term used in one patent need not have the same meaning when used in an entirely separate patent." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1318 (Fed. Cir. 2005)."). In fact, the Federal Circuit has repeatedly refused to review other patents when construing terms of a patent-in-suit, even when the patents share a common inventor and common subject matter. *See, e.g., Goldenberg v. Cytogen, Inc.,* 373 F.3d 1158, 1167-68 (Fed. Cir. 2004); *Abbott Labs. v. Dey, L.P.,* 287 F.3d 1097, 1104-05 (Fed. Cir. 2002).

Finally, Centocor points to Abbott's agreement on the construction of two other terms in the patents-in-suit that use the word "includes" as evidence that the language that follows this

---

[6] Nevertheless, the construction advanced by Centocor and adopted by the court in that litigation, is consistent with the construction Abbott is proposing in this case. (*See* Gunther Ex. 18, [Centocor's] Opening Claim Construction Br. in *Centocor, Inc., et al. v. Abbott Laboratories, et al.*, Civil Action No. 2:07cv139, at 19 [redacted]).)

word is definitional, rather than exemplary. (Centocor Mem. at 11-12.) However, just because Abbott agreed to narrow the definitions of these two terms in negotiating the parties' agreed-upon constructions does not mean that any language in the common specification that follows the word includes is necessarily a definition. *See, e.g.*, *SanDisk Corp.*, 415 F.3d at 1284; *Travel Sentry, Inc., v. Tropp,* Nos. 06-6415, 08-4446, 2010 WL 3522250, at *13 (E.D.N.Y. Sept. 10, 2010) ("by stating that the method "includes" certain steps, the description tacitly acknowledges that there may very well be other steps to which it has not called attention"). While such a narrow definition may have made sense with regard to the specification language for the two claim terms on which the parties reached agreement, for the reasons already discussed above, a definitional reading of the specification language that follows the term "human antibody" simply does not make sense.

C. Centocor's Position in the Interference Contradicts Its Current Argument

It is Centocor, and not Abbott, that is now taking a different position with regard to the term "human antibody" than it did in the interference proceedings. In order to provoke the interference and argue that Centocor patent application was entitled to priority over Abbott's '128 patent, Centocor conceded that, as described and claimed in Centocor's patent application, the antibody in its accused product, Stelara, and the only antibody in Centocor's application that was part of the interference, was a human antibody, as that term is used in Abbott's '128 Patent specification and claims. Indeed, Centocor's Declaration of Interference specifically recites Count I of the interference as "[a]n isolated *human antibody* according to claim 1 of U.S. Application 10/912,994 or claim 1 of U.S. Patent 6,914,128." (Gunther Decl. Ex. 9 at 5 (emphasis added).) Without an admission that its antibody was a human antibody under both Centocor's patent application and Abbott's '128 Patent, Centocor would not have been able to

seek an interference. Now, however, Centocor is improperly taking the opposite stance in arguing that its antibody is not a human antibody.

Likewise, Centocor's current position is inconsistent with the testimony of its witnesses during the interference. For instance, Centocor's Director of Protein Engineering, Dr. Karyn T. O'Neil, testified that a "human antibody" is any antibody that has "over 80 percent" "sequence identity" with "or sequence homology" to a human gene or human germline sequences. (Gunther Decl. Ex. 17, O'Neil Tr. (Apr. 22, 2008) at 12:21-13:23.) This understanding of "human antibody" is much broader than the "up to twenty positions replaced with amino acid residues" construction that Centocor now advances. Similarly, Centocor's Manager in Research Operations and Strategic Planning, Kimberly Staquet, testified during the interference that "[a] human antibody is an antibody that is fully human, does not contain any portions from other species." (Gunther Decl. Ex. 19, Staquet Tr. (Oct. 23, 2008) at 37:7-10.) This definition is fully in line with Abbott's proposed construction.

Centocor's about-face in this litigation further points to the fact that its belated argument, raised for the first time on the eve of the close of fact discovery, lacks merit. Centocor should not be allowed to continually seek delay in resolving this case. For all of these reasons, Centocor's proposed claim construction should be rejected.

IV. CONCLUSION

For the reasons set forth herein, Abbott respectfully requests that the Court reject Centocor's attempt to assert a new, untimely non-infringement theory. If the Court does reach the claim construction issue raised by Centocor, Abbott requests that the Court construe the "human antibody" claim term to mean "an antibody that is derived from human DNA and not from the DNA of any non-human species."

Respectfully Submitted,

Dated: March 7, 2011

/s/ Robert J. Gunther, Jr.

Robert J. Gunther, Jr. (admitted *pro hac vice*)
Jane M. Love (admitted *pro hac vice*)
Violetta G. Watson (admitted *pro hac vice*)
Julia A. Grimes (admitted *pro hac vice*)
WILMER CUTLER PICKERING
HALE AND DORR LLP
399 Park Avenue
New York, New York 10022
Tel: (212) 230-8800
Fax: (212) 230-8888

William F. Lee (BBO #291960)
Anne M. McLaughlin (BBO # 666081)
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, Massachusetts 02109
Tel: (617) 526-6000
Fax: (617) 526-5000

William G. McElwain (BBO # 332510)
Amy K. Wigmore (admitted *pro hac vice*)
Rachel L. Weiner (admitted *pro hac vice*)
WILMER CUTLER PICKERING
HALE and DORR LLP
1875 Pennsylvania Avenue, NW
Washington, DC 20006
Tel: (202) 663-6000
Fax: (202) 663-6363

William W. Kim (admitted *pro hac vice*)
WILMER CUTLER PICKERING
HALE and DORR LLP
950 Page Mill Road
Palo Alto, California 94304
Tel: (650) 858-6000
Fax: (650) 858-6100

Attorneys for Abbott GmbH & Co., KG, Abbott Bioresearch Center, Inc., and Abbott Biotechnology, Ltd.

CERTIFICATE OF SERVICE

I certify that, on March 7, 2011, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/Robert J. Gunther, Jr.